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EXAMINER

BAUM, STUART F

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 07/23/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/787,737

Applicant(s)

KAKIMOTO, TATSUO

Examiner

Stuart F. Baum

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 7-10, 12-22 and 24-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1, 7-10, 15, 17 and 18 is/are allowed.
- 6) ☒ Claim(s) 2, 3, 12-14, 16, 19-22 and 24-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed 5/7/2003 has been entered.
Claims 1-3, 7-10, 12-22, and 24-34 are pending.
Claims 4-6, 11, and 23 have been canceled.
Claims 28-34 have been newly added.
2. Claims 1-3, 7-10, 12-22 and 24-34 are examined in the present office action.
3. Rejections and objections not set forth below are withdrawn.
4. The text of those sections of Title 35, U.S. Code not included in this office action can be found in a prior office action.

Indefiniteness

5. Claims 2-3, 12-14, 16, 19-22, and 24-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 2, the metes and bounds of “participates” has not been defined. It is not clear to what extent a protein has to be involved in differentiation to be considered as a “participant”. For example, proteins involved in photosynthesis, could be considered as participating in differentiation, because without photosynthesis, the plant would not grow. All subsequent recitations of “participates” are also rejected.

In claim 2, line 4, the word “sequence” should be inserted after the word “acid”.

In claim 2, line 6, the word “shoot” should be replaced with --shoots--. All subsequent recitations of “shoot” are also rejected.

In claim 2, the metes and bounds of “homeodomain-like” cannot be determined since Applicant has not adequately defined this term. All subsequent recitations of “homeodomain-like” are also rejected. This rejection is maintained for the reasons of record set forth in the Official action mailed 11/7/2002. Applicant’s arguments filed 5/7/2003 have been fully considered but they are not persuasive.

The Applicants contend that the specification discloses information which renders the recitation “homeodomain-like” definite. The specification purportedly defines the term both functionally and structurally. Functionally, Applicants state that a protein that is involved in differentiation and that has a homeodomain-like sequence is a protein that is involved in adventitious shoot formation, branching, and formation of leaves, flowers or the like, i.e., a protein that induces the formation of adventitious shoots, branching and the like (page 10, 3rd paragraph). Applicants define homeodomain structurally as a 61 amino acid sequence encoded by a homeobox region, the polypeptide of which has a secondary structure of a helix-turn-helix, comprising three α helixes and which recognizes a specific nucleotide sequence thereby to bind DNA.

The Office contends that Applicants arguments are not persuasive. In regards to structure, the homeodomain is a DNA binding domain with a characteristic secondary structure comprising a helix-turn-helix. Homeodomains bind specific sequences of DNA but different

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homeodomain proteins bind different but yet, specific, DNA sequences. There can be a lot of variation in the 61 amino acid sequence and yet, the protein can still comprise the helix-turn-helix secondary structure and be classified as having a homeodomain. In regards to function, Applicants definition is still vague as homeodomain proteins have been shown to be involved in development, and one major process in development is cell division, of which shoot formation or adventitious shoot formation is a part. Because Applicant has not defined the specific biological function, i.e., which sequence of DNA their homeodomain binds to and what role their protein plays in transcription, and because Applicant has not defined the specific limits delineating a homeodomain-like amino acid sequence, the recitation of “homeodomain-like” is indefinite.

In claim 3, 6th line, insert --and-- before the word “further”.

In claim 31, the metes and bounds of “a part” have not been defined. Applicant has not specified the minimum or maximum number of amino acids that are encompassed by the recitation “a part”.

In claim 32, replace “homology” with --sequence identity--. The meaning of the word “homologous” includes an evolutionary component, that is not defined.

Scope of Enablement

6. Claims 2-3, 19-22, and 24-34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to a polynucleotide encoding a protein whose amino acid sequence is SEQ ID NO:2, including a vector and transformed host cell, plant, and plant cell and methods for inducing adventitious shoot formation and branching does not

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reasonably provide enablement for claims drawn to an isolated polynucleotide sequence encoding a protein whose amino acid sequence has been modified by the addition or deletion of one or a plurality of amino acids and/or replacement with other amino acids in the amino acid sequence of SEQ ID NO:2, said sequence having at least 20% amino acid identity to SEQ ID NO:2, or wherein the number of amino acids of SEQ ID NO:2 that have been modified is 50, 25, or 10 or less; an isolated polynucleotide that hybridizes to the nucleic acid having the nucleotide sequence of SEQ ID NO:1 or a portion thereof, under stringent conditions or wherein the polynucleotide has a length of 75% or greater of the entire sequence of SEQ ID NO:1 and includes at least one amino acid of the homeodomain, or wherein the sequence that hybridizes to SEQ ID NO:1 has a sequence identity of 50%, 70% or 90% when compared to SEQ ID NO:1; a vector, host, plant or plant cell comprising an above mentioned sequence; and methods for inducing differentiation, adventitious shoot formation, or branching comprising a sequence of claim 2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. This rejection is maintained for the reasons of record set forth in the Official action mailed 11/7/2002. Applicant's arguments filed 5/7/2003 have been fully considered but they are not persuasive.

Applicants contend that one skilled in the art could make modifications to the protein sequence and screen the protein to determine whether or not it retains the recited activity. In regards to claims 3, Applicant contends that one skilled in the art could screen proteins which hybridize and determine whether the encoded protein has the recited activity. Applicants state that since the hybridization conditions are "stringent", there would not be a high amount to

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screen through, and one skilled in the art could screen sequences for the required activity.

Applicants further state that claims 28-34 limit the scope of polynucleotides being claimed by limiting the number of amino acids to be modified, and specifying that the length of sequences hybridizing to SEQ ID NO:1 be at least 75% of the length of SEQ ID NO:1 and include a part or all of the homeodomain sequence. In addition, Applicants have limited the scope of “differentiation” to only include adventitious shoot formation and branching.

The Office asserts that Applicants have not defined an activity for their recited invention, they only specify that expression of SEQ ID NO:1 causes the phenotype of the plant to change. Adventitious shoot formation and branching are developmental processes common to many genes. Applicants have not disclosed a specific activity that can be assayed, and used to determine if isolated sequences fall within the scope of their invention. In addition, Applicants have not taught which amino acids are important for the proper activity of the protein and which amino acids can be deleted, added or substituted and still maintain the proper activity of the protein. While one skilled in the art can readily make deletions, additions and substitutions, no guidance is given as to what mutations are tolerated. Applicants have also not disclosed the hybridization conditions that are used to isolate the claimed sequences as disclosed in claim 3. The Office also asserts that new claim 31 now claims a sequence with only one amino acid from the homeodomain and as such it is unclear what one skilled in the art would do with a sequence only comprising one amino acid from a homeodomain, given that one amino acid would not produce the appropriate secondary structure to facilitate DNA binding. The Office would also like to point out that proteins do not hybridize to nucleic acid sequences as Applicants have disclosed on page 13, 2nd paragraph. In conclusion, given the reasons stated in the last office

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action and the remarks stated above, and given the claim breadth, undue experimentation would be required to practice the broadly claimed invention.

Written Description

7. Claims 2-3, 19-22, and 24-34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 11/7/2002. Applicant's arguments filed 5/7/2003 have been fully considered but they are not persuasive.

Applicants contend that a cloned cDNA sequence exhibiting 86% sequence identity within the homeodomain and 40% sequence identity in the entire region with the MSH cDNA, produced more branching when overexpressed in *Arabidopsis*. Based on this disclosure, Applicants contend that they are in possession of the invention as recited in the claims.

The Office contends that while Applicants may be in possession of the disclosed sequence, one skilled in the art cannot predictably determine the structure of sequences encompassed by the claims based upon the disclosure of the specific sequences. Also, given the lack of disclosed conserved domains, one skilled in the art would not be able to predict the structure of other sequences within the claimed genus. Based on the broad claim language, Applicants are not in possession of all the claimed sequences.

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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8. Claim 31 rejected under 35 U.S.C. 102(a) as being anticipated by Olsson et al (October, 1999, WO99/50417).

The claim is drawn to a polynucleotide sequence which hybridizes to SEQ ID NO:1, has a length of 75% or greater of the entire sequence of SEQ ID NO:1, includes a part of the homeodomain and would be involved in adventitious shoot formation or branching.

Olsson et al teach a sequence from *Populus* that is a homeobox protein and is at least 75% of the length of SEQ ID NO:1. This gene when over-expressed would be involved in adventitious shoot meristem formation because of its role in the vascular cambium, which is also a meristem, and as such, Olsson et al anticipate the claimed invention.

9. Claims 2-3 and 19-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Kotani et al (1997, DNA Research 4:291-293).

The claims are drawn to an isolated polynucleotide encoding a protein that has a sequence identity having at least 20% amino acid sequence identity to SEQ ID NO:2 and would hybridize to a sequence set forth in SEQ ID NO:1, and the encoded polypeptide would induce adventitious shoots and branching, including vector and host transformed therewith.

Kotani et al disclose a DNA sequence that encodes a protein having 76.9% sequence identity to SEQ ID NO:2 and the nucleic acid sequence would hybridize to SEQ ID NO:1. For purposes of molecular biology, the nucleic acid sequence would be in a vector transformed into a host cell. Since claim 19 does not further limit the structure of the polynucleotides as claimed in claim 2, but only set forth characteristics of adventitious shoots and branching, thus the

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polynucleotides of Kotani et al would inherently possess the recited function, and as such, Kotani et al anticipate the claimed invention.

10. SEQ ID NO:1 encoding SEQ ID NO:2 are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest an isolated polynucleotide of SEQ ID NO:1 encoding SEQ ID NO:2.

11. Claims 1, 7-10, 15, and 17-18 are allowable.

12. Claims 2-3, 12-14, 16, 19-22 and 24-34 are rejected.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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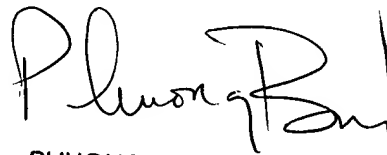
14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart Baum whose telephone number is (703) 305-6997. The examiner can normally be reached on Monday-Friday 8:30AM – 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 or (703) 305-3014 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist, who may be contacted at 308-0196.

Stuart F. Baum Ph.D.

July 10, 2003


PHUONG T. BUI
PRIMARY EXAMINER